

Charles M. Lizza  
William C. Baton  
Sarah A. Sullivan  
Alexander L. Callo  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102  
(973) 286-6700

*Attorneys for Plaintiffs  
Alkermes, Inc. and  
Alkermes Pharma Ireland Limited*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

ALKERMES, INC. and ALKERMES  
PHARMA IRELAND LIMITED,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 20-12470 (MCA)(MAH)

(Filed Electronically)

**STIPULATED CONSENT JUDGMENT AND INJUNCTION**

Whereas Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited (together, “Plaintiffs”) and Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) have agreed to resolution of this action,

IT IS HEREBY STIPULATED AND AGREED, by and between Plaintiffs and Teva, through their undersigned counsel of record, that:

1. In the event that the claims of U.S. Patent No. 7,919,499 (the “’499 Patent”) asserted against Teva are not held invalid or unenforceable, then, absent a license or other

authorization from Plaintiffs, the '499 Patent would be infringed by any unlicensed manufacture, sale, offer for sale, use, or importation in the United States of the generic product that is the subject of Teva's Abbreviated New Drug Application (the "Teva Product").

2. Teva and anyone acting on the behalf of Teva, except as expressly licensed by Plaintiffs, will be enjoined until expiration of the '499 Patent from (i) making, using, offering to sell, selling, or importing the Teva Product in the United States, and (ii) participating in the profits from making, using, offering to sell, selling, or importing the Teva Product in the United States, and (iii) indemnifying others with respect to any making, using, offering to sell, selling, or importing the Teva Product in the United States.

3. Notwithstanding any provision of the foregoing, Teva shall be entitled to contest the infringement, validity, and/or enforceability of the '499 Patent in any future litigation pertaining to any product that is not a generic VIVITROL product.

4. Each party will bear its own attorneys' fees and costs.

5. This Court will retain jurisdiction to enforce this Stipulated Consent Judgment and Injunction and the parties' resolution of this matter.

6. Plaintiffs acknowledge that Teva is entitled to maintain its Paragraph IV certification to the '499 Patent pursuant to 21 C.F.R. § 314.94(a)(12)(v) and this resolution has no impact on the final approval of Teva's ANDA.

7. The Clerk of Court is directed to enter this Stipulated Consent Judgment and Injunction.

Dated: August 30, 2023

SO STIPULATED:

s/ Charles M. Lizza

Charles M. Lizza  
William C. Baton  
Sarah A. Sullivan  
Alexander L. Callo  
SAUL EWING LLP  
One Riverfront Plaza, Suite 1520  
Newark, NJ 07102  
(973) 286-6700

s/ Liza M. Walsh

Liza M. Walsh  
Christine I Gannon  
Jessica K. Formichella  
WALSH PIZZI O'REILLY FALANGA LLP  
Three Gateway Center  
100 Mulberry Street, 15<sup>th</sup> Floor  
Newark, N.J. 07102  
(973) 757-1100

OF COUNSEL:

Bruce M. Wexler  
Isaac S. Ashkenazi  
Max H. Yusem  
PAUL HASTINGS LLP  
200 Park Avenue  
New York, New York 10166

*Attorneys for Plaintiffs  
Alkermes, Inc. and  
Alkermes Pharma Ireland Limited*

OF COUNSEL:

J.C. Rozendaal  
Uma Everett  
Tyler Liu  
Christina Dashe  
STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.  
1100 New York Ave., NW, Suite 600  
Washington, DC 20005  
(202) 371-2600

*Attorneys for Defendant  
Teva Pharmaceuticals USA, Inc.*

SO ORDERED this 18 day of Sept, 2023.



Hon. Madeline C. Arleo, U.S.D.J.